



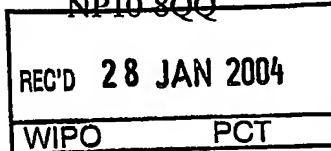
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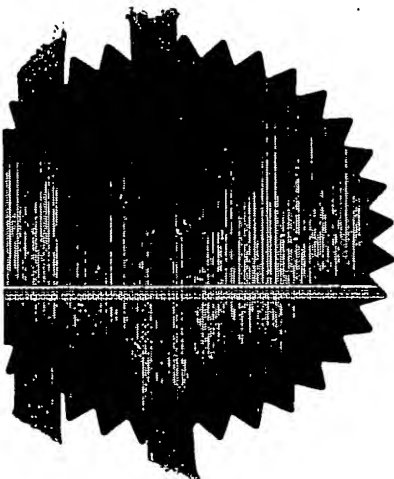


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3. Full name, address and postcode of the or of each applicant (underline all surnames)

The Medical House plc  
210 Newhall Road  
Attercliffe  
Sheffield  
S9 2QJ

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

United Kingdom

4. Title of the invention

Needleless Injection Device

5. Name of your agent (if you have one)

Vanessa J STAINTHORPE

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

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Date

Vanessa J Stainthorpe

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Vanessa J Stainthorpe

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## NEEDLELESS INJECTION DEVICE

This invention relates to the field of needleless injection devices of the type used, for example, for subcutaneous injection of insulin or growth hormone.

Needleless injection devices (or "needleless injectors") are well known and are designed to deliver a predetermined dose of a drug, for example insulin, by means of a spring-loaded or gas-powered syringe. One typical such needleless injector is described in US 5,782,802 [VitaJet Corp].

The device described in US 5,782,802 is designed to be easily refilled and reused by a single user with the correct dose of a medicament required at each injection. The device comprises basically of:

- a) an injection head comprising a transparent thermoplastic generally cylindrical nozzle and a thermoplastic piston tip, both supplied to the user in a sterile pack;
- b) a spring-powered unit with means to quickly attach and detach the injection head from this spring-powered unit; and
- c) a pre-filled special vial (containing the medicament) which connects to the injection head, or alternatively an adaptor which is attached to a commercially-available vial of medicament.

A dose of medicament is loaded into the device of US 5,782,802 by turning a dosage drum in an anti-clockwise direction so as to draw a quantity of medicament into the nozzle. When activated by the user, the injector delivers the medicament by expelling it rapidly through a small aperture in the nozzle so that the medicament

passes through the patient's skin.

5 The delivery of a medicament using a needleless injector is typically much less traumatic than using a conventional syringe with a needle. This is because the nozzle aperture is usually of smaller diameter than a hypodermic needle and secondly because the medicament is delivered more rapidly using a needleless injector than by using a needle.

10

Conventional injectors of the type described above have a relatively noisy operation owing to the use of ball bearings in the discharge mechanism. The discharge mechanism of US5,782,802 is described therein with reference to Figure 1 (see column 5, line 39 - column 6 line 22). In particular, ball bearings 48 are trapped between the ram's rear neck 36 and the inner front end of the bushing 44. In this position, the ball bearings 48 lock the ram 34 to the discharge mechanism 32. In order to discharge the device, the bushing 44 has to move forward allowing ball bearings 48 to move outward, away from the ram's neck 36, which consequently allows the ram's rear shoulder 38 to pass through, pushed vigorously by the fully compressed main spring 22.

25

The movement of the ball bearings 48 is only limited by the confines of the relevant parts of the device in which they are located. It is possible that the ball bearings will "rattle" within those confines, especially given the great force stored in the fully compressed main spring which is suddenly released upon discharge of the device, causing the ball bearings to be pushed vigorously. This "rattle" means that the device has a relatively noisy discharge operation.

35

The "rattle" (i.e. reverberation) of the ball bearings also has an adverse effect on the smoothness with which the medicament is delivered. It is important to minimise lateral movement of the injector during operation else  
5 trauma to the skin may result and therefore there is a desire to improve the smoothness of the injector's operation.

It is therefore an object of the present invention to  
10 provide a needleless injector which seeks to minimise the trauma to a patient's skin at the injection site, whilst also providing a quiet and smooth delivery of medicament to the patient.

15 According to a first aspect of the invention there is provided a needleless injection device comprising

a cylinder for medicament having an injection nozzle at a forward end thereof and an opening at its rearward end;

20 a piston sliding in the cylinder through said open end, in use, to drive the medicament through the nozzle;

a ram to drive the piston into the cylinder and having a longitudinal axis; and

an energy accumulator to drive the ram when  
25 discharged and disposed between the ram and a discharge assembly, a rear end of the ram extending into said discharge assembly; wherein

the discharge assembly comprises a retention member fixed in the assembly, said retention member having a  
30 plurality of retention elements spaced around and adapted to locate on a collar of the ram when in a charged position of the ram, and a release ring surrounding said retention elements to prevent radial outward displacement thereof and discharge of the ram; and wherein

35 axial displacement of said release ring releases

said retention elements and causes discharge of the ram by said accumulator;  
characterised in that said retention elements are integral with said retention member and move into and out  
5 of engagement with said collar by deformation of the material of said retention member.

Since the ram is discharged by means of deformation of the material of the retention elements, the "rattle" or  
10 reverberation of the prior art device, caused by ball bearings or the like, is eliminated. The discharge of the device is much smoother, more controlled and quieter than that of conventional devices.

15 Preferably, said retention member comprises a collet having radially-spreadable fingers, which collet in use moves between said first position in which said fingers engage with said ram and said second position in which said fingers spread radially out of engagement with said  
20 ram. Ideally, said collet fingers each have an enlarged head which can engage with a groove or recess in said ram.

Preferably, said collet fingers are biased radially-  
25 inwardly.

Preferably, said release ring comprises a collet lock sleeve which limits outward radial movement of said collet fingers. Ideally, axial movement of said collet  
30 lock sleeve is limited by abutment thereof against said collet fingers.

Preferably, said collet lock sleeve and said collet fingers are respectively provided with cooperating  
35 tapered surfaces.

In a preferred embodiment said energy accumulator is a compression spring.

5 According to a second aspect of the invention there is provided a nozzle lock assembly which enables a nozzle to be releasably attached to a needleless injection device upon insertion of a nozzle into an end thereof, the nozzle lock assembly including

10 on one of said nozzle or said end of the injection device, a twist cap containing a moveable spacer which has a non-circular aperture therethrough; and

15 on the other of said nozzle or said end of the injection device a protrusion having a correspondingly shaped non-circular outer surface which, if aligned therewith, can pass through said non-circular aperture,

20 wherein, upon twisting of said twist cap, the moveable spacer twists with respect to said protrusion so that the non-circular aperture of the spacer can be selectively brought into and out of alignment with the non-circular outer surface of said protrusion, so that said protrusion is  
25 respectively either free to move in or out of said aperture or is trapped therein by said moveable spacer.

30 Preferably, said twist cap is located on said end of the injection device and said protrusion is located on said nozzle.

35 Preferably, the nozzle lock assembly further comprises a second protrusion having the same non-circular outer surface and being axially spaced from the first



protrusion.

Preferably, said non-circular aperture and said non-circular outer surface are substantially triangular.

5

Preferably, the nozzle lock assembly further comprises a mark on said twist cap which indicates the relative alignment of the non-circular apertures.

10 According to a third aspect of the invention there is provided a needleless injection device including a nozzle lock assembly as described in any of the preceding paragraphs.

15 According to a fourth aspect of the invention there is provided a discharge assembly, suitable for use in a needleless injection device as described in any of the preceding paragraphs, comprising a retention member fixed in the assembly, said retention member having a plurality  
20 of retention elements spaced around and adapted to locate on a collar of a ram when in a charged position of the ram, and a release ring surrounding said retention elements to prevent radial outward displacement thereof and discharge of the ram; and wherein

25 axial displacement of said retention ring releases said retention elements and causes discharge of the ram by an energy accumulator;  
characterised in that said retention elements are integral with said release ring and move into and out of  
30 engagement with said collar by deformation of the material of said release ring and retention elements.

Preferred embodiments of the present invention will now be more particularly described, by way of example only,  
35 with reference to the accompanying drawings wherein:

Figure 1 is a perspective view of a needleless injector embodying the first aspect of the invention;

5 Figure 2 is an exploded view of the injector shown in Figure 1;

Figure 3 is a perspective view of the housing assembly;

10 Figure 4 is a perspective view of the ram assembly;

Figure 5 is a longitudinal cross-sectional view of the needleless injector of Figure 1, in a just-discharged condition;

15

Figure 6 is a longitudinal cross-sectional view of the needleless injector of Figure 1, with the spring primed;

20 Figure 7 is a longitudinal cross-sectional view of the needleless injector of Figure 1, ready to be discharged;

Figure 8 is a perspective view of the vial assembly;

25 Figure 9 is an exploded view of the vial assembly of Figure 8;

Figure 10 is a perspective view of the nozzle assembly;

30 Figure 11 is an exploded view of the nozzle assembly of Figure 10;

Figure 12 is a perspective view of the nozzle lock assembly;

35 Figure 13 is an exploded view of the nozzle lock assembly

of Figure 12;

Figure 14 is a perspective view of the ram assembly;

5 Figure 15 is an exploded view of the ram assembly of Figure 14;

Figure 16 is a perspective view of the discharge assembly;

10

Figure 17 is an exploded view of the discharge assembly of Figure 16;

15 Figure 18 is a cross-sectional perspective view of part of the discharge assembly;

Figure 19 is a perspective view, partly in cross-section of the assembled discharge and ram assemblies;

20 Figure 20 is a perspective view of the firing assembly; and

Figure 21 is an exploded view of the firing assembly of Figure 20.

25

Throughout the following description, reference to a "forward" direction means the direction which is towards the patient when the injector is in use. The "forward" end of the injector is the end nearest the patient's skin when the injector is in use. Similarly, reference to a  
30 "rearward" direction means the direction which is away from the patient and the "rearward" end of the injector is the end furthest from the patient's skin when the injector is in use.

35

As shown in Figure 1, the injector comprises a nozzle assembly 20, a nozzle lock assembly 30, a housing assembly 40 and a firing assembly 50. Not visible in Figure 1, as they are located inside the housing assembly 40, are a ram assembly 60 (see Figure 4) and a discharge assembly 70 (see Figure 2). Each of the assemblies will be described in more detail below with reference to the appropriate Figures.

Referring to Figure 3, the main housing assembly 40 comprises a front housing 42, a central housing 43 and a rear housing 44. The central and rear housings 43, 44 are fixed with respect to one another. The front housing 42 is rotatable with respect to the combined central and rear housing.

A vial cartridge 10 is illustrated in Figures 8 and 9 which is designed to accept a standard sized proprietary medicament vial, to facilitate the loading of the medicament into the injector.

The vial cartridge is shown in exploded form in Figure 9, including a standard 3mm medicament vial 11. The cartridge 10 comprises a housing 12 inside which the vial 11 can be slid until it abuts a puncturing means 13. A seal washer 14 and a bung 15 are fitted on a first end 16 of the housing to prevent egress of the medicament. When the vial 11 is placed inside the housing 12, a push nut 18 is screwed onto a second end 17 of the cartridge so as to urge the vial towards the puncturing means which causes the end of the vial at the first end 16 of the cartridge to be punctured by the puncturing means 13. A pressure lock 19 assists in retaining the bung 15 on the first end 16.

35

Upon removal of the bung 15, the cartridge is ready to be attached to the nozzle assembly 20 of the injector so as to enable medicament to be loaded into the injector.

5 The nozzle assembly 20 is shown in Figures 10 and 11. The assembly comprises a single hole nozzle 21 having two aligned substantially triangular formations 22A, 22B at the rearward end thereof. Between the triangular formations 22A, 22B is a slot 23. A piston 24 has a  
10 nozzle ram 25 press-fitted to or integrally-moulded with the forward end thereof and the piston/nozzle ram assembly fits within the bore of the nozzle 21. A cover seal 26 and a nozzle cover 27 can be press-fitted to the forward end of the nozzle 21, as shown in Figure 10.

15

The nozzle lock assembly 30 is shown in Figures 12 and 13. It provides a mechanism for releasably locking the nozzle assembly 20 to the rest of the injector so that it is easy to remove and replace the nozzle assembly 20 at  
20 will. The nozzle assembly needs replacing, typically weekly, so it is advantageous to be able to do so quickly and easily.

The nozzle lock assembly includes a nozzle twist cap 31 which is used to actuate the nozzle lock. Inside the  
25 twist cap 31 is a retaining clip 32 which has a triangular aperture therethrough large enough for the triangular protrusions 22A, 22B of the nozzle assembly to pass through. The retaining clip 32 fixes the nozzle  
30 lock assembly 30 to the end of the injection device. Adjacent the retaining clip 32 is a lock yoke spacer 33 which has a similarly-sized triangular aperture therethrough. The lock yoke spacer 33 has two external protruding lugs 33A, 33B. These lugs engage in  
35 corresponding slots inside the twist cap 31 so that, upon

twisting the twist cap 31, the lock yoke spacer 33 is driven in the same direction by the interaction between the lugs and corresponding slots. This enables the lock yoke spacer 33 to be moved between a first, open position in which its triangular aperture is aligned with that of the retaining clip 32 and a second, closed position in which the triangular apertures are offset by, for example, 60 degrees. The retaining clip 32 is fixed with respect to the rest of the injection device and hence does not twist when the twist cap is moved. An arrow 34 is marked on the twist cap 31 to indicate which position the lock yoke spacer 33 is currently in.

In order to insert the rearward end of the nozzle assembly 20 into the nozzle lock assembly 30, it is necessary for the lock yoke spacer 33 to be in the open position. The nozzle assembly can be inserted far enough that the lock yoke spacer 33 is located at the position of the slot 23 on the nozzle 21. Upon twisting the twist cap to the closed position, the lock yoke spacer 33 twists through 60 degrees so that it becomes out of alignment with the triangular protrusions 22A, 22B. This prevents withdrawal of the nozzle 21 from the nozzle lock assembly.

The ram assembly 60 will now be described with reference to Figures 4, 14 and 15. The ram 61 is the part which, in use, is urged forward in a rapid motion to move a plunger in order to expel medicament from the injector. The ram itself comprises two parts: a forward ram portion 61A and a rear splined portion 61B. These two portions are, in use, fixedly attached to one another.

At the forward end of the forward ram portion 61A is a screw-threaded portion 62 which, when the ram assembly is

assembled, co-operates with an internal screw-thread on a pressure nut 63. The forward end 64 of the pressure nut 63 is enlarged which defines the forwardmost limit of a chamber (described below) in which a main spring is situated. Relative movement of the pressure nut 63 and front ram portion 61A (by using the screw thread) changes the volume of the chamber and this is described in more detail below. A sleeve 65 forms the cylindrical wall of the chamber, as shown in Figure 14. The pressure nut 63 is fixed with respect to the sleeve 65.

Figures 16-19 show the discharge assembly 70 which is used to lock the ram 61A, 61B in a position ready to fire (having compressed the main spring as described below) and then to release the spring-loaded ram at the desired moment upon actuation of a firing mechanism.

The discharge assembly 70 comprises a cylindrical housing 71 whose forward end is closed except for an aperture 72 of sufficient diameter to receive the rear splined portion 61B of the ram assembly. The rear end of the housing 71 is open and has an internal screw thread 100. A housing nut 73 screws into the rear end of the housing 71. The housing nut 73 has an aperture therethrough of sufficient diameter to receive a splined pickup 74.

The rear splined portion 61B of the ram assembly includes an annular groove 66 thereon as illustrated in Figures 14, 15 and 19.

The discharge assembly includes a retention member, for example a collet 75, having a plurality of fingers 76 ("retention elements"), each having an enlarged head 76A. The enlarged heads 76A are suitably sized to fit into the groove 66 of the rear splined portion 61B of the ram

assembly. This can be seen in Figure 19. Also visible in Figure 19 is the main spring 77.

The rearmost assembly in the injection device is the firing assembly 50, illustrated in Figures 1, 20 and 21. The firing assembly includes a rear housing nut 51 which has protrusions or a textured surface thereon. In use, as described below, the user grips the rear housing nut 51 and rotates it with respect to the main body of the device and the protrusions or textured surface aids gripping by the user.

As shown in Figure 21, mountable on the rearward side of the rear housing nut 51 is a firing button 52. Axial depression of the firing button 52 actuates the injection device. The firing assembly also includes a combined key lock and pressure adjustment facility. This facility provides a safety "key lock" which prevents inadvertant firing of the injection device. The same device also includes a facility for adjusting the force with which the injection device fires a medicament into the patient. The operation of this facility will be described in more detail below, once the basic operation of the injection device has been described.

The key stages in the basic operation of the injection device will now be described in turn. Figure 5 shows the injection device in a just-discharged condition, i.e. ready to be prepared for firing again. With reference to Figure 5, it can be seen that the ram 61 is in a forward position with its forward end 64 abutting the housing. The main spring 77 is at its maximum extent, having just been discharged. The collet fingers 76 are radially-spread and a collet lock sleeve 78 is positioned forward of the collet fingers 76, with a secondary spring 80



being compressed. Although the secondary spring 80 is compressed, rearward axial movement of the collet lock sleeve 78 is prevented by its abutment against the collet fingers 76. An annular gap 84 is present between the  
5 collet lock sleeve 78 and the release fingers 81.

#### **Loading a Vial into the Vial Assembly**

Referring to Figures 8 and 9, firstly, the end cap on a vial 11 of the desired medicament is pulled off. The  
10 push nut 18 is unscrewed from the end of the vial assembly 10 and the vial 11 is dropped into the vial housing 12. As the push nut 18 is screwed back onto the end of the vial housing 12, the vial 11 is urged against puncturing means 13 which punctures the end of the vial  
15 11. The vial bung 15 prevents egress of the medicament from the vial at this stage.

#### **Priming the Spring**

Before a dose of medicament can be loaded, it is  
20 necessary to prime the main spring 77 so that the injection device is ready to fire. Referring to Figure 6, the main spring 77 is housed within a chamber having a cylindrical wall formed by sleeve 65 (see Figures 6 and 14). The forward end of the chamber is defined by the  
25 forward end 64 of the pressure nut 63. The rearward end of the chamber is defined by the forward end of the housing 71 (see Figures 6 and 18).

The front housing 42, illustrated in Figures 1 and 3, is  
30 rotatable with respect to the central and rear housings 43, 44.

Referring again to Figure 6, when the central and rear housings 43, 44 are held stationary, and the front  
35 housing 42 is rotated in a clockwise direction (when

viewed from the rear end of the injection device), the screw thread 45 at the rear end of the front housing advances rearwardly along a corresponding screw thread on the central and rear housings in the direction indicated by the arrow in Figure 6. Since the discharge assembly housing 71 is fixed with respect to the central and rear housings, this causes a shortening of the chamber containing the main spring as the front housing moves rearwardly, thus compressing the main spring 77.

10

Figure 6 shows the situation in which the chamber has been reduced to its minimum length and the spring 77 is fully compressed. In this position, the enlarged heads 76A of the collet 75 drop into the groove 66 on the rear splined portion 61B of the ram. The collet fingers 76 have a tendency to spring radially inwardly toward one another which is why they readily drop into the groove 66 when they reach this portion of narrowed diameter. However, the compressive force stored in the main spring 77 means that the ram has a great tendency to move axially forward (which would force the collet fingers 76 radially apart). The location of the collet fingers 76 in groove 66 is not sufficient alone to resist this. Therefore a collet lock sleeve 78 is employed which has a tapered internal surface 79. The collet lock sleeve 78 is biased rearwardly by a secondary spring 80 which is under compression. When the collet fingers 76 drop into groove 66, the collet lock sleeve 78 moves rearwardly sufficient to transmit rearward force to the firing button 52 so that the button is firmly positioned ready for actuation. The tapered surface 79 engages the tapered surfaces of the enlarged heads 76A of the collet fingers. This has the effect of preventing further rearward movement of the collet lock sleeve 78 and also prevents radial movement of the collet fingers which

35

therefore remain engaged in the groove 66. The gap 84 (see Figure 5) which was present between the collet lock sleeve 78 and the release fingers 81 has closed. The ram is now held in a fixed position relative to the central and rear housings 43, 44. The main spring is now primed and the injection device is ready for a dose of medicament to be loaded.

#### **Loading a Dose of Medicament into the Nozzle**

10 The vial bung 15 is removed from the loaded vial assembly 10, which is then pushed onto the nozzle assembly 20 on the forward end of the assembled injection device (Figure 1). The medicament in the vial is now in communication with the nozzle 21.

15

With reference to Figure 6, although the spring has been primed, an injection cannot yet be delivered because the forward end of the ram 61 abuts the front housing 42 and the dose of medicament has not yet been loaded. It is necessary to retract or wind back the ram in order to load the medicament and to get the injection device into a condition ready for firing. This is achieved by anti-clockwise rotation (when the injection device is viewed from the rear) of the front housing 42 with respect to the central and rear housings 43, 44.

20 With reference to Figure 7, this anti-clockwise rotation causes the screw thread 45 at the rear of the front housing 42 to advance forwards in the direction indicated by the arrow (with respect to the corresponding screw thread on the central and rear housings 43, 44). The chamber in which the main spring 77 is situated does not get longer because the ram 61 is held in a fixed position with respect to the central and rear housings 43, 44 by the collet 76 and collet lock sleeve 78. Instead, the

30

35

front housing 42 advances forwards, leaving the whole ram assembly, main spring and discharge assembly fixed with respect to the central and rear housings 43, 44. This creates a space at the forward end of the injection device into which the ram can be driven when the device is discharged.

The effect of this is to cause the piston/nozzle ram 24, 25 to retract away from the nozzle aperture, drawing the medicament into the nozzle. A dose indicator 41 indicates, through a window 46 in the main housing assembly 40, the volume of the medicament dose loaded into the nozzle. In addition or alternatively, an audible dose indicator could also be provided. When the desired dose has been loaded into the nozzle, the vial assembly 10 can be removed.

#### Releasing Safety Lock

Referring to Figures 20 and 21, the firing assembly 50 includes a key lock 53 which has a shaped aperture therethrough having a circular region 53A and a linear region 53B. The linear region 53B is, at its narrowest portion, of a similar diameter to the splined pickup 74. The splined pickup 74 is provided with two axially-spaced grooves which are visible in Figures 16-19. The forwardmost groove 82 is generally circular in lateral cross-section. The rearmost groove 83 has a generally hexagonal lateral cross-section and by "diameter" is meant the distance between two parallel sides of the hexagon.

In normal use (i.e. other than for adjusting the firing force as described later), the key lock 53 is axially aligned with the forwardmost groove 82. The key lock 53 can be slid laterally between two positions; one in which

the linear region 53B is aligned with the groove 83 and a second in which the circular region 53A is aligned with the groove 82. In the former position, the splined pickup is confined by the interaction of the linear region 53B with the groove 82 and the injection device is prevented from being fired. In order to be able to fire the device, the sliding switch 54 needs to be slid so as to move the circular region 53A into alignment with the groove 82. In this position, the splined pickup 74 is free to move axially within the key lock 53 (and hence the injection device can be fired).

#### **Firing the Injection Device**

With the injection device held against the patient's skin at the desired injection site, the button 52 is pressed. This applies a forward force to the splined pickup 74 (see Figures 17-19) which in turn transmits this force to release fingers 81. The release fingers 81 push forwardly against the collet lock sleeve 78 which causes the tapered surface 79 thereof to disengage from the tapered, enlarged heads 76A of the collet 75. The slightest disengagement of the collet lock sleeve 78 from the collet allows the stored force in the main spring 77 to cause the collet fingers 76 to move radially-outward out of the groove 66 which releases the ram (as shown in Figure 5). Once free to move, the ram is driven forcefully forward by the main spring 77. The front ram portion 61A drives the piston 24 and nozzle ram 25 into the nozzle, where the medicament is located, causing the medicament to be ejected from the nozzle and into the patient. Having been fired, the injection device is in the condition illustrated in Figure 5.

#### **Adjusting the Firing Force**

The firing force of the injection device is determined by

the properties of the main spring 77, in particular the degree to which it is compressed before the device is fired. There is sometimes a desire to adjust the firing force of an injection device since, for example, in certain patients a powerful device may causes bruising or trauma at the injection site. Conventional needleless injection devices can be adjusted by the provision of "comfort rings" which limit the force which can be stored in the main spring. However, the injection device needs to be disassembled in order to insert the comfort rings and this brings the risk of injury caused by inadvertant firing and/or incorrect reassembly of the device. The injection device described herein enables the firing force to be adjusted without the need to take apart the device.

Referring again to Figures 16-21, in order to adjust the firing force, the rear housing nut 51 is pulled axially rearwardly, i.e. away from the front end of the device. This causes the key lock 53 to move out of alignment with the groove 82 and to drop into alignment with the rearmost groove 83. The rearmost groove 83 has a generally hexagonal lateral cross section which is closely engaged within the linear region 53B. By rotating the rear housing nut 51, the key lock 53 is also rotated which causes the key lock 53 to be used in the manner of a spanner to rotate the splined pickup 74 and hence the whole ram 61A, 61B with respect to the housing assembly 40.

During this rotation of the ram 61A, 61B, the screw-threaded portion 62 at the front end of the ram (see Figure 15) co-operates with the screw thread on nut 63 to reduce or enlarge the volume of the chamber in which the main spring 77 is confined (depending upon the direction

in which the ram is rotated). By varying the volume of the chamber in which the main spring is confined, the maximum compressive firing force which can be stored in the spring is also varied.

## CLAIMS

1. A needleless injection device comprising  
a cylinder for medicament having an injection  
5 nozzle at a forward end thereof and an opening at  
its rearward end;  
a piston sliding in the cylinder through said  
open end, in use, to drive the medicament through  
the nozzle;  
10 a ram to drive the piston into the cylinder and  
having a longitudinal axis; and  
an energy accumulator to drive the ram when  
discharged and disposed between the ram and a  
discharge assembly, a rear end of the ram extending  
15 into said discharge assembly; wherein  
the discharge assembly comprises a retention  
member fixed in the assembly, said retention member  
having a plurality of retention elements spaced  
around and adapted to locate on a collar of the ram  
20 when in a charged position of the ram, and a release  
ring surrounding said retention elements to prevent  
radial outward displacement thereof and discharge of  
the ram; and wherein  
axial displacement of said release ring  
25 releases said retention elements and causes  
discharge of the ram by said accumulator;  
characterised in that said retention elements are  
integral with said retention member and move into and out  
of engagement with said collar by deformation of the  
30 material of said retention member.
2. A device as claimed in claim 1 wherein said  
retention member comprise a collet having radially-  
spreadable fingers, which collet in use moves  
35 between said first position in which said fingers



engage with said ram and said second position in which said fingers spread radially out of engagement with said ram.

- 5     3.     A device as claimed in claim 2 wherein said collet fingers each have an enlarged head which can engage with a groove or recess in said ram.
- 10     4.     A device as claimed in claim 2 or claim 3 wherein said collet fingers are biased radially-inwardly.
- 15     5.     A device as claimed in any of claims 2 to 4 wherein said release ring comprises a collet lock sleeve which limits outward radial movement of said collet fingers.
- 20     6.     A device as claimed in claim 5 wherein axial movement of said collet lock sleeve is limited by abutment thereof against said collet fingers.
- 25     7.     A device as claimed in claim 5 or claim 6 wherein said collet lock sleeve and said collet fingers are respectively provided with cooperating tapered surfaces.
- 30     8.     A device as claimed in any of the preceding claims wherein said energy accumulator is a compression spring.
- 35     9.     A nozzle lock assembly which enables a nozzle to be releasably attached to a needleless injection device upon insertion of a nozzle into an end thereof, the nozzle lock assembly including  
         on one of said nozzle or said end of the injection device, a twist cap containing a moveable

spacer which has a non-circular aperture therethrough; and

5 on the other of said nozzle or said end of the injection device a protrusion having a correspondingly shaped non-circular outer surface which, if aligned therewith, can pass through said non-circular aperture,

10 wherein, upon twisting of said twist cap, the moveable spacer twists with respect to said protrusion so that the non-circular aperture of the spacer can be selectively brought into and out of alignment with the non-circular outer surface of said protrusion, so that said protrusion is respectively either free to move in or out of said 15 aperture or is trapped therein by said moveable spacer.

10. A nozzle lock assembly as claimed in claim 9 wherein said twist cap is located on said end of the 20 injection device and said protrusion is located on said nozzle.

11. A nozzle lock assembly as claimed in claim 9 or claim 10 further comprising a second protrusion 25 having the same non-circular outer surface and being axially spaced from the first protrusion.

12. A nozzle lock assembly as claimed in any of claims 9 to 11 wherein said non-circular aperture and said 30 non-circular outer surface are substantially triangular.

13. A nozzle lock assembly as claimed in any of claims 9 to 12 further comprising a mark on said twist cap 35 which indicates the relative alignment of the non-

circular aperture and the protrusion.

14. A needleless injection device including a nozzle lock assembly as claimed in any of claims 9 to 13.
- 5
15. A needleless injection device as claimed in any of claims 1 to 8 including a nozzle lock assembly as claimed in any of claims 9 to 13.
- 10
16. A needleless injection device substantially as described herein with reference to any appropriate combination of the accompanying drawings.
- 15
17. A discharge assembly, suitable for use in a needleless injection device as claimed in any of claims 1-8 or 14-16, comprising a retention member fixed in the assembly, said retention member having a plurality of retention elements spaced around and adapted to locate on a collar of a ram when in a charged position of the ram, and a release ring surrounding said retention elements to prevent radial outward displacement thereof and discharge of the ram; and wherein
- 20
- axial displacement of said retention ring releases said retention elements and causes discharge of the ram by an energy accumulator; characterised in that said retention elements are integral with said release ring and move into and out of engagement with said collar by deformation of the
- 25
- material of said release ring and retention elements.
- 30

## ABSTRACT

A needleless injection device comprising

5 a cylinder for medicine having an injection nozzle at a forward end thereof and an opening at its rearward end;

a piston sliding in the cylinder through said open end, in use, to drive the medicine through the nozzle;

10 a ram to drive the piston into the cylinder and having a longitudinal axis; and

a mechanical energy accumulator to drive the ram when discharged and disposed between the ram and a discharge assembly, a rear end of the ram extending into said discharge assembly; wherein

15 the discharge assembly comprises a retention member fixed in the assembly, said retention member having a plurality of retention elements spaced around and adapted to locate on a collar of the ram when in a charged position of the ram, and a release ring surrounding said retention elements to prevent radial outward displacement thereof and discharge of the ram; and wherein

axial displacement of said release ring releases said retention elements and causes discharge of the ram by said accumulator;

25 characterised in that said retention elements are integral with said retention member and move into and out of engagement with said collar by deformation of the material of said retention member.

30 [Figure 1]

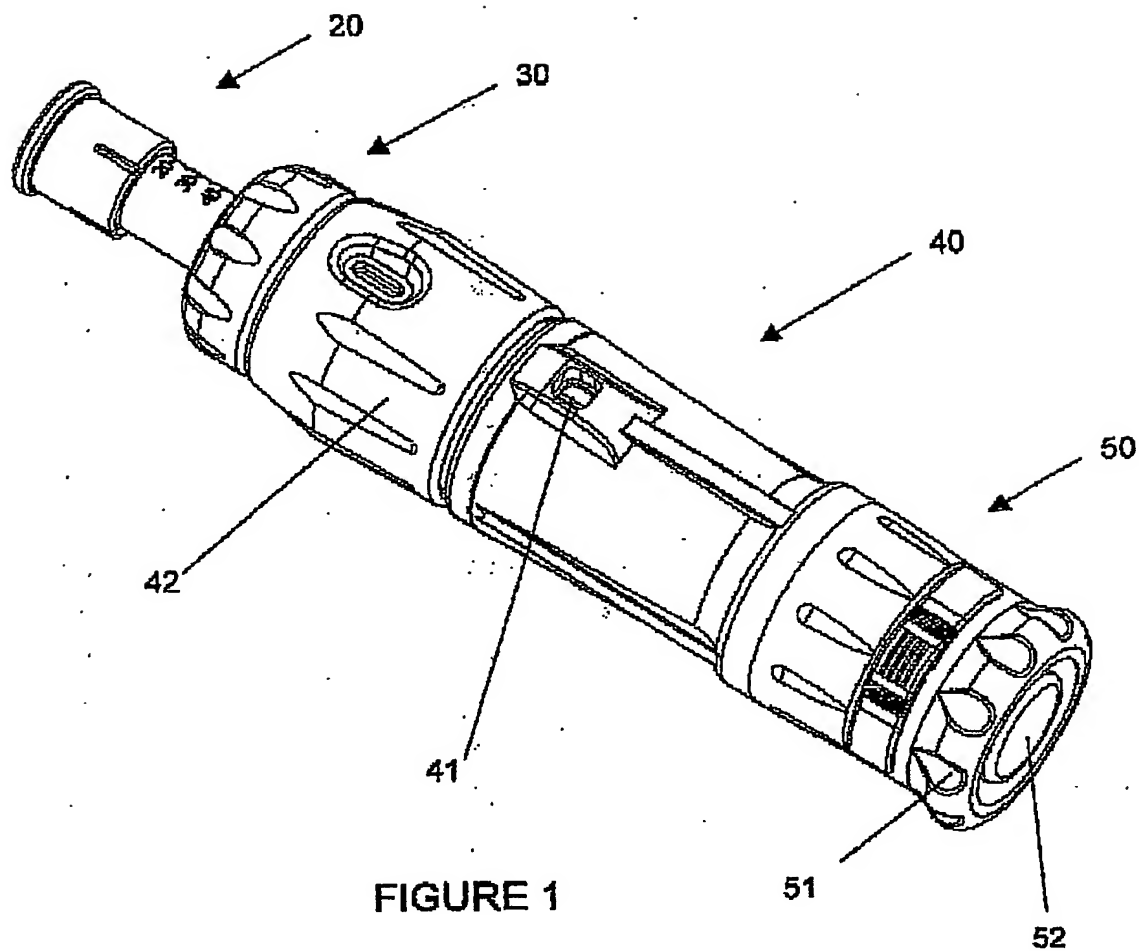
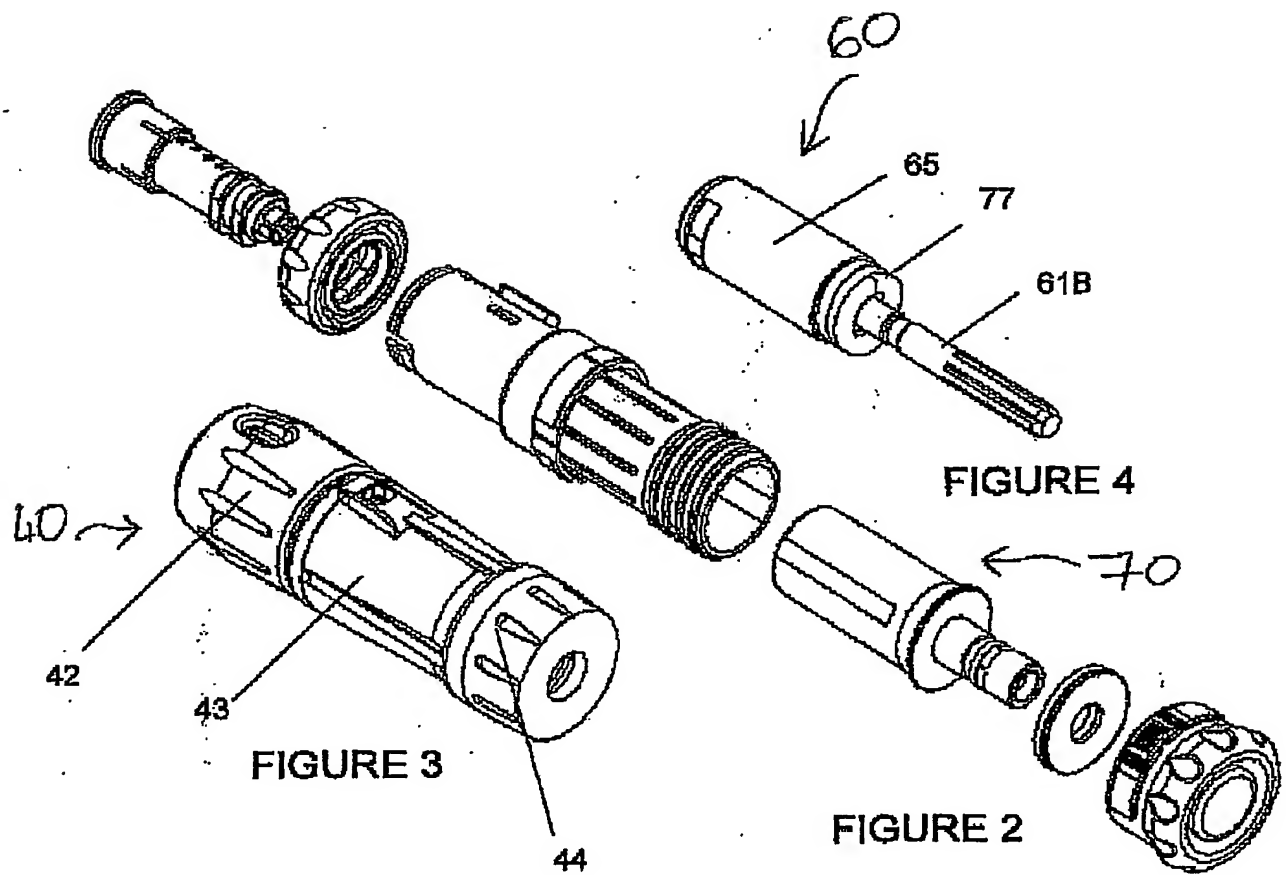


FIGURE 1



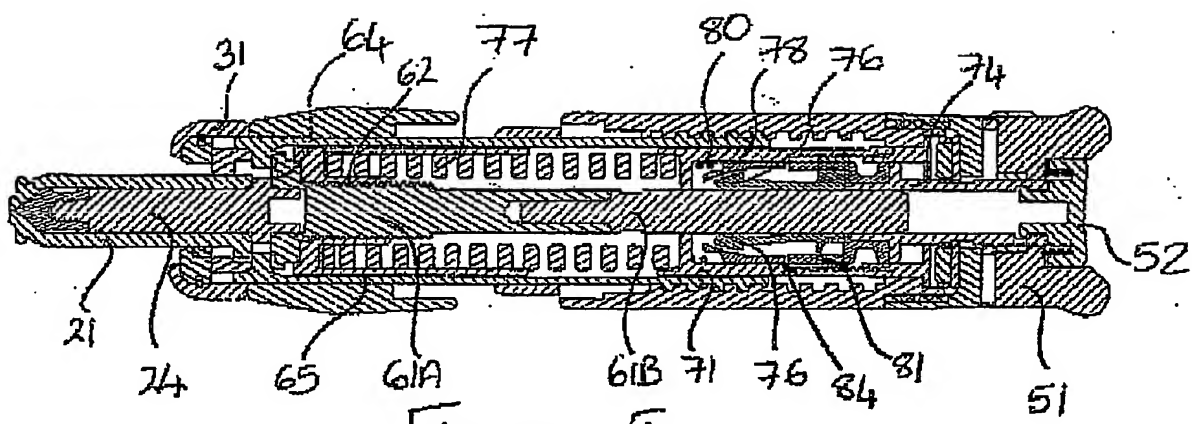


FIGURE 5

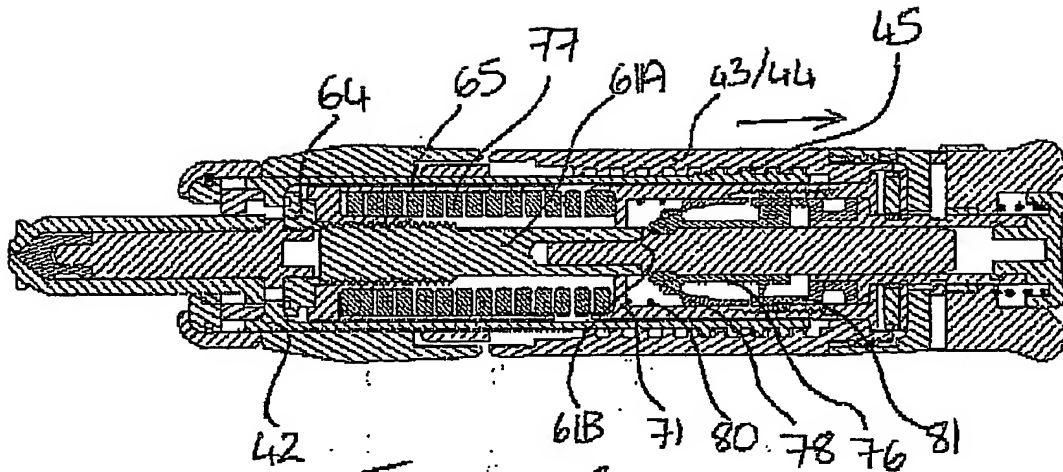
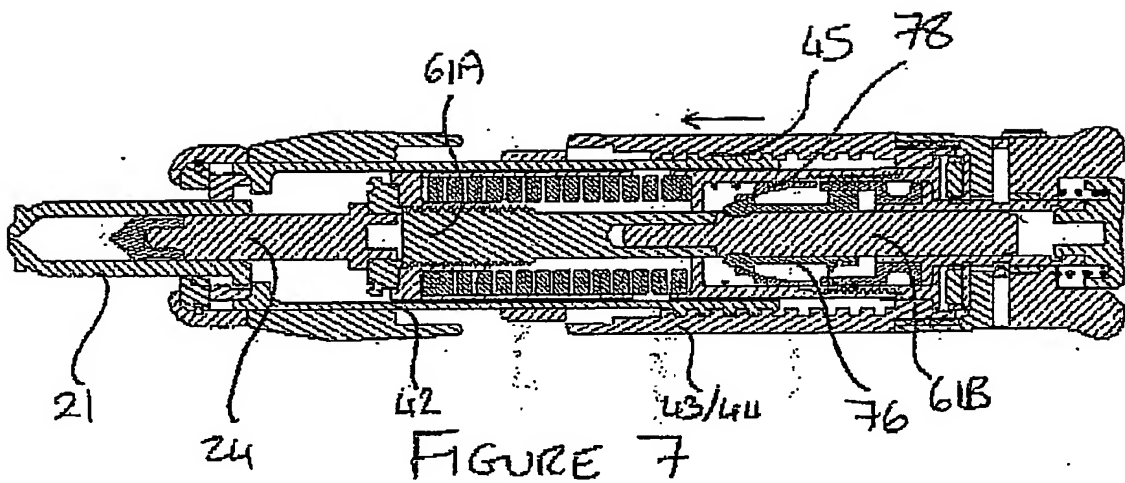
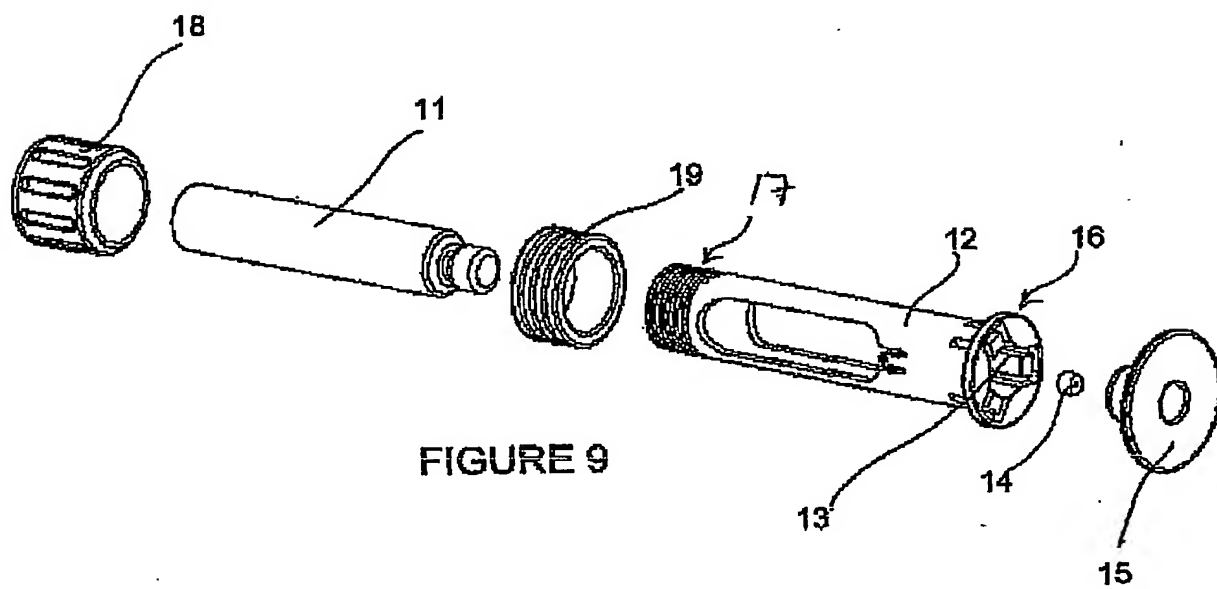
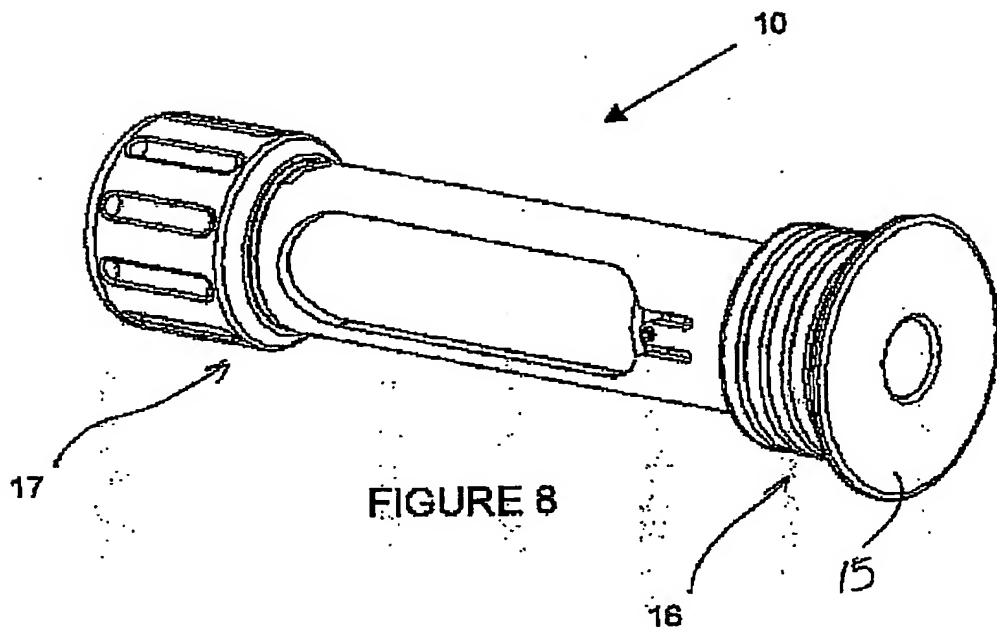


FIGURE 6







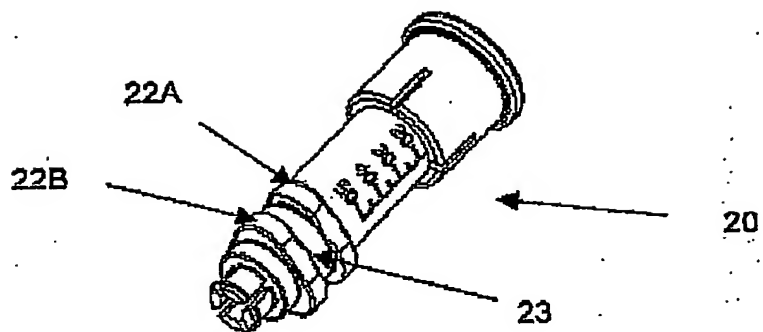


FIGURE 10

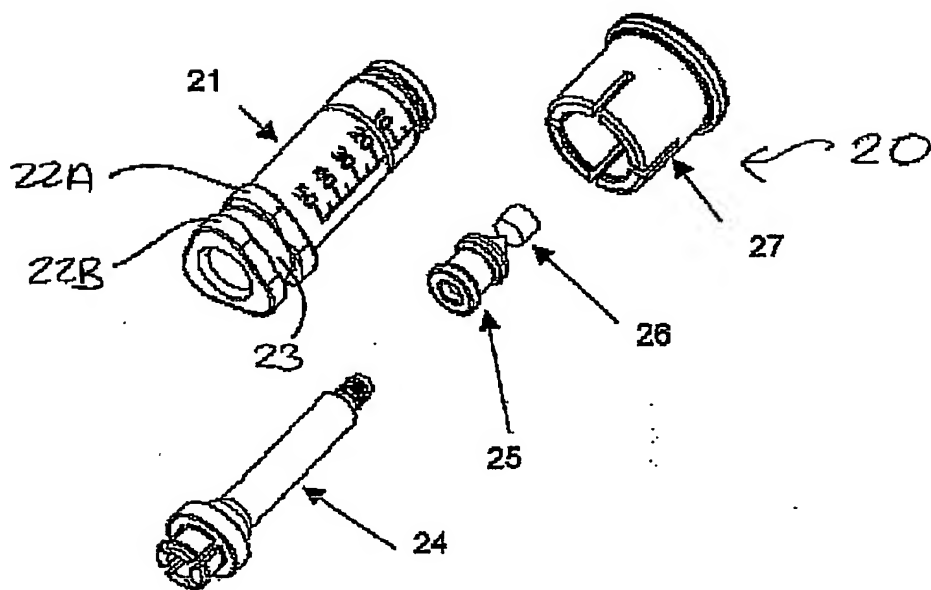


FIGURE 11

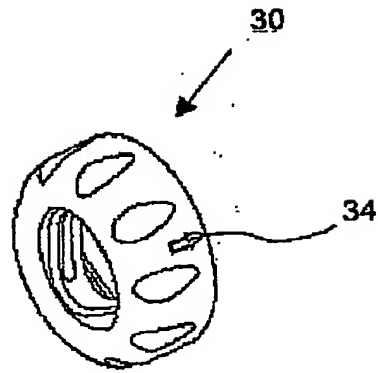


FIGURE 12

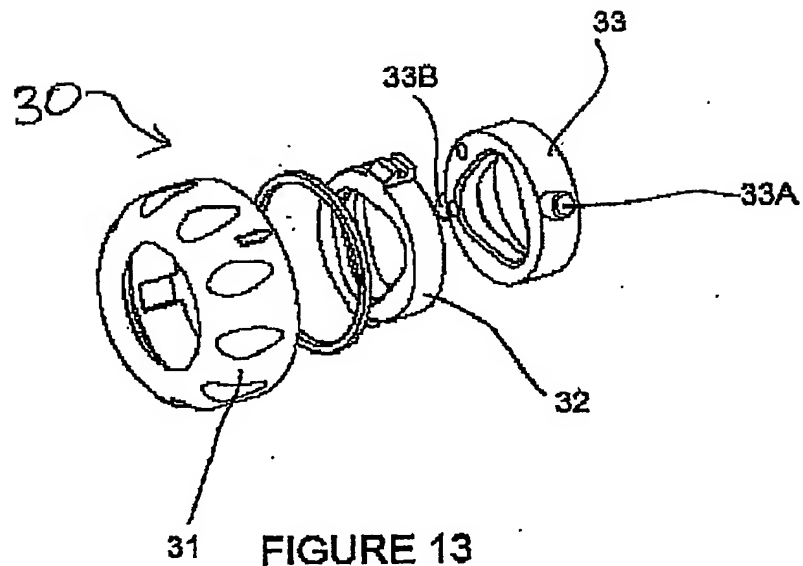
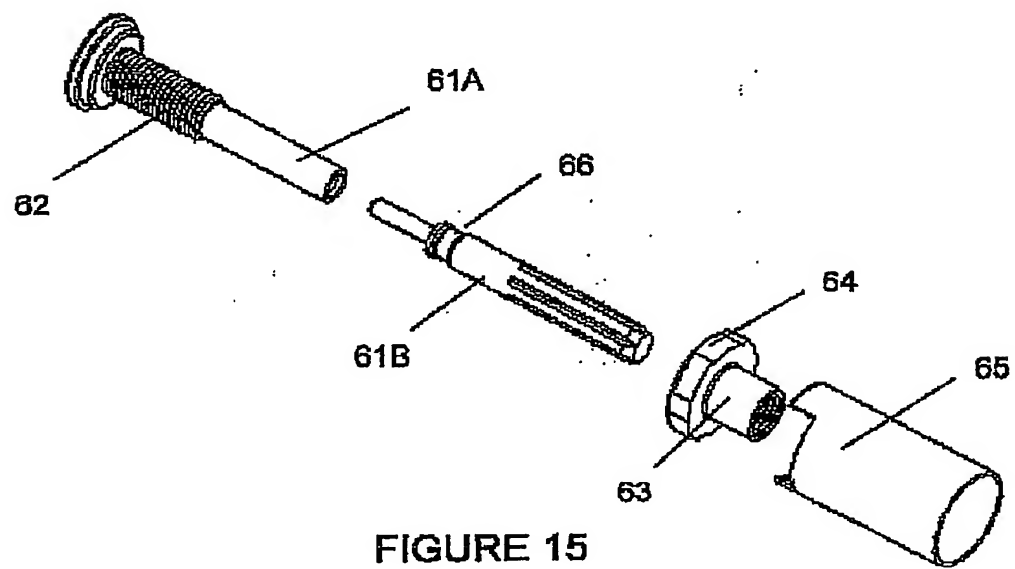
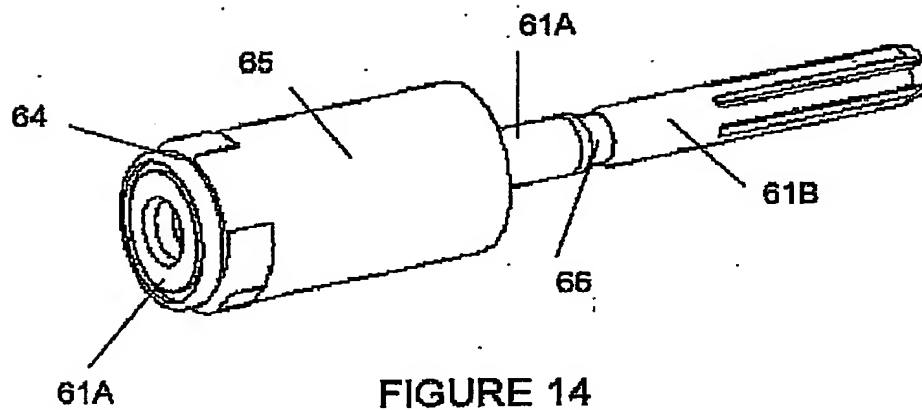
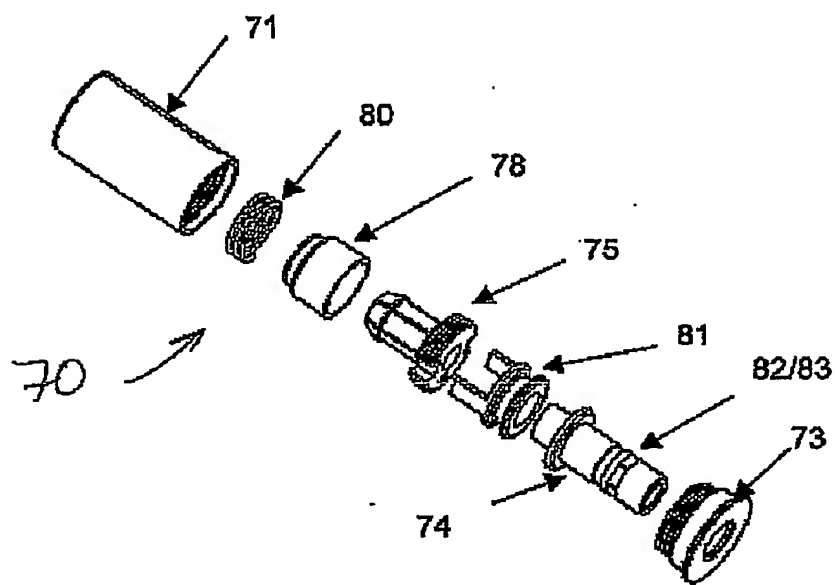
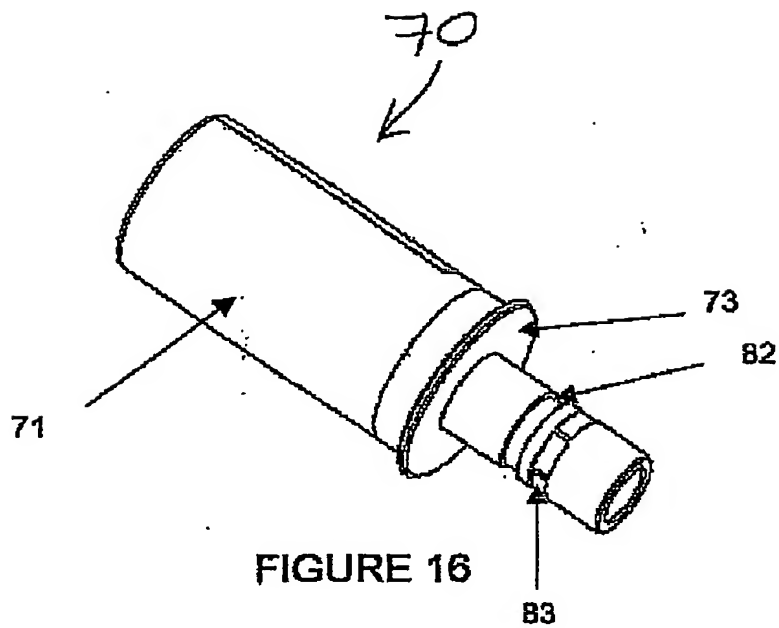
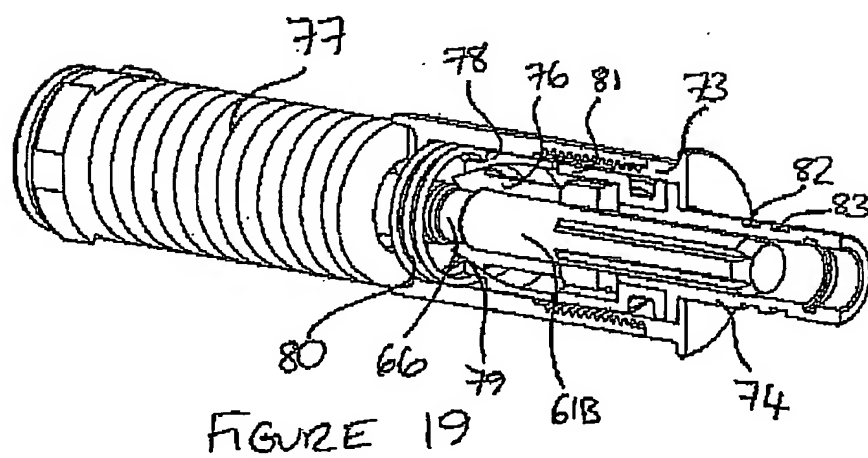
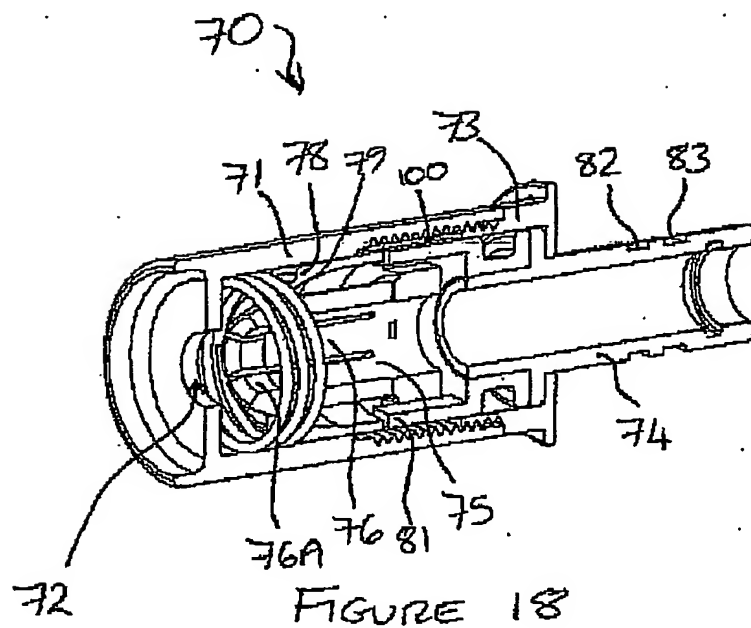


FIGURE 13







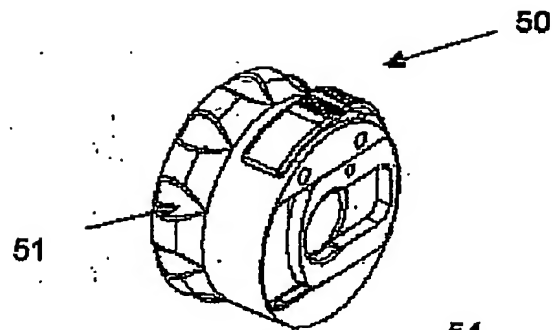


FIGURE 20

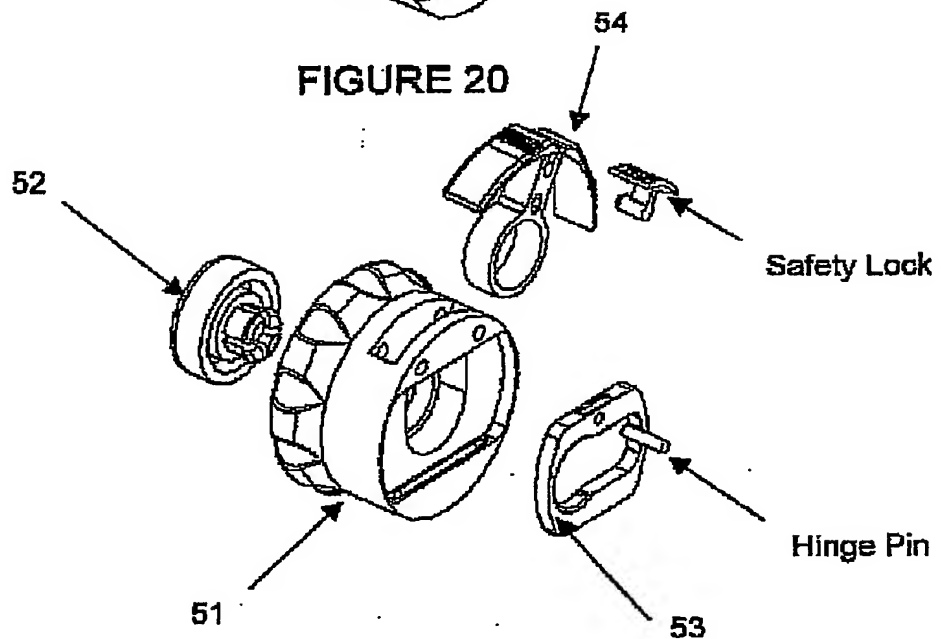


FIGURE 21



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